



**To:** SPU Community  
**From:** Les Steele, Vice President for Academic Affairs  
*Les Steele*  
**Re:** Federal Wide Assurance Regarding Human Subjects Research  
**Date:** July 13, 2006

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### **SPU INSTITUTIONAL REVIEW BOARD CHARTER**

In accord with Federal Regulations 45CFR46<sup>1</sup>, Seattle Pacific University has provided the Department of Health and Human Services an assurance that it will comply with federal regulations for human subjects' protections. This Federal Wide Assurance, known as FWA, covers the responsibilities of the University, the IRB, and investigators. Under the FWA, all research involving human subjects at SPU—not just federally funded research—is subject to IRB review and approval. As the signatory to the FWA, I charge the IRB with the following tasks and responsibilities.

The Institutional Review Board (IRB) shall review and have authority to approve, require changes in prior to approval, or disapprove research activities involving human subjects which are conducted at or sponsored by SPU, including research activities (a) performed by SPU faculty, staff, and students, (b) performed in SPU facilities, or (c) otherwise supported by University resources which are under the control of SPU officials. The IRB shall also have the responsibility and authority to adopt appropriate procedures adequate to assure compliance with the approved consent process and other requirements for the protection of human subjects.

### **IRB AUTHORITY AND RESPONSIBILITIES**

To fulfill the requirements of DHHS regulations and this policy, the IRB shall have the following authority and responsibilities:

1. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations, state law, and institutional policy.
2. The IRB shall require signed informed consent by Human Subjects where required by 45CFR46.116 & 117.
3. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give

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<sup>1</sup> Including subparts B, C & D

the investigator an opportunity to respond in person or in writing.

4. Except when an expedited review is used, the IRB shall review proposed research at convened meetings at which a quorum of the members of the IRB are present. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
5. The IRB shall not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. The IRB shall ensure appropriate training for Investigators whose research includes Human Subjects.
7. The IRB shall conduct continuing reviews of research at intervals appropriate to the degree of risk but not less than once per year. The IRB shall have the authority to determine which research requires review more often than annually.
8. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with its approval.
9. The IRB shall have the authority to suspend or terminate approval or require modification to research that has been associated with unexpected serious harm to subjects (e. g. Adverse event). Any suspension or termination of approval shall include a statement of reasons for the IRB action and shall be reported promptly by the IRB Chair to the investigator, the investigator's sponsor (if applicable) and the VPAA.
10. The IRB will maintain appropriate records regarding investigator training, research projects, and federal certificates.
11. The IRB shall publish its policies and procedures that detail requirements for research with Human Subjects.
12. The IRB will ensure that the University meets its obligations for Federal Wide Assurance and make appropriate changes in light of new regulations.
13. The IRB is responsible for reporting to the Vice President for Academic Affairs any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.
14. The IRB shall report annually to Faculty Council on the status of its work.

**Reporting Relationship:**

The Institutional Review Board will report to the Vice President of Academic Affairs.

**Composition:**

The IRB will be comprised of no fewer than five members: all of whom are knowledgeable in the issues of human research, not entirely men or women, one of whom has primary concerns in scientific areas, one of whom has primary concerns in non-scientific areas, one of whom is not affiliated with the college, none that have any conflicting interest with any project to be reviewed. At least three members will hold faculty contracts, one of whom will chair the board. Appointments will be made by the VPAA per the federal regulations upon the recommendations of the appropriate Deans.